



ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2019-0238; FRL-10016-77]

1,4-Dioxane; Supplemental Analysis to the Draft Toxic Substances Control Act (TSCA)

Risk Evaluation; Notice of Availability and Public Comment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) is announcing the availability of and soliciting public comment on a supplemental analysis to the draft risk evaluation of 1,4-dioxane under the Toxic Substances Control Act (TSCA). EPA conducts risk evaluations to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment without consideration of costs or other nonrisk factors, including an unreasonable risk to potentially exposed or susceptible subpopulations, under the conditions of use. This supplemental analysis has been developed in response to public and peer review comments on the draft risk evaluation, and includes additional conditions of use for 1,4-dioxane as a by-product in consumer products, as well as an analysis of recreational activities in ambient/surface water as an exposure pathway under all conditions of use included in the draft risk evaluation and this supplemental analysis. EPA is announcing the opening of a docket for a 20-day comment period to allow the public to review the supplemental analysis to the draft risk evaluation.

DATES: Comments must be received on or before **[INSERT DATE 20 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2019-0238, on the Federal eRulemaking Portal at <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose

disclosure is restricted by statute. To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Due to the public health concerns related to COVID-19, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Yvette Selby-Mohamadu, Existing Chemicals Risk Assessment Division, Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001; telephone number: (202) 564-5245; email address: selby-mohamadu.yvette@epa.gov.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: TSCA-Hotline@epa.gov.

SUPPLEMENTARY INFORMATION

I. General Information

A. What action is EPA taking?

Public and peer review comment on the 1,4-dioxane draft risk evaluation suggested that the Agency had omitted both conditions of use associated with 1,4-dioxane as a by-product in consumer products and potential exposure from the ambient surface water pathway. EPA has provided a supplemental analysis to the draft risk evaluation to include these two additions and seeks public comment. Therefore, EPA is providing public notice and an opportunity to comment on this supplemental draft risk evaluation prior to publishing a final risk evaluation.

B. Does this action apply to me?

This action is directed to the public in general. This action may, however, be of interest to those involved in the manufacture, processing, distribution, use, disposal, and/or the assessment

of risks involving chemical substances and mixtures. You may be potentially affected by this action if you manufacture (defined under TSCA to include import), process, distribute in commerce, use or dispose 1,4-dioxane. Since other entities may also be interested, the Agency has not attempted to describe all the specific entities and corresponding NAICS codes for entities that may be interested in or affected by this action.

C. What is the Agency's authority for taking this action?

TSCA section 6(b) requires that EPA conduct risk evaluations on existing chemical substances and identifies the minimum components EPA must include in all chemical substance risk evaluations. 15 U.S.C. 2605(b). The risk evaluation must not consider costs or other nonrisk factors. 15 U.S.C. 2605(b)(4)(F)(iii). TSCA section 6(b)(4)(H) requires EPA to provide public notice and an opportunity for comment on a draft risk evaluation prior to publishing a final risk evaluation. The specific risk evaluation process is set out in 40 CFR part 702 and summarized on EPA's website at <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluations-existing-chemicals-under-tsca>.

D. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit CBI information to EPA through *regulations.gov* or email. If your comments contain any information that you consider to be CBI or otherwise protected, please contact the Peer Review Leader listed under **FOR FURTHER INFORMATION CONTACT** to obtain special instructions before submitting your comments.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at <http://www.epa.gov/dockets/comments.html>.

II. Background

A. What is EPA's risk evaluation process for existing chemicals under TSCA?

The risk evaluation process is the second step in EPA's existing chemical process under TSCA, following prioritization and before risk management. As this chemical is one of the first ten chemical substances undergoing risk evaluation, the chemical substance was not required to

go through prioritization (81 FR 91927, December 19, 2016) (FRL-9956-47). The purpose of conducting risk evaluations is to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment under the conditions of use, including an unreasonable risk to a relevant potentially exposed or susceptible subpopulation. As part of this process, EPA must evaluate both hazard and exposure, not consider costs or other nonrisk factors, use reasonably available information and approaches in a manner that is consistent with the requirements in TSCA for the use of the best available science, and ensure decisions are based on the weight of the scientific evidence.

The specific risk evaluation process that EPA has established by rule to implement the statutory process is set out in 40 CFR part 702 and summarized on EPA's website at <http://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluations-existing-chemicals-under-tsca>. As explained in the preamble to EPA's final rule on procedures for risk evaluation (82 FR 33726, July 20, 2017) (FRL-9964-38), the specific regulatory process set out in 40 CFR part 702, subpart B will be followed for the first ten chemical substances undergoing risk evaluation to the maximum extent practicable.

In September 2019, EPA published a draft risk evaluation that was subject to peer review and public comment. EPA reviewed the peer review report from the Science Advisory Committee on Chemicals (SACC) and public comments and has supplemented the risk evaluation in response to these comments as appropriate. The public comments and peer review report are in Docket EPA-HQ-OPPT-2019-0238 at www.regulations.gov. Prior to the publication of the draft risk evaluation, EPA made available the scope and problem formulation, and solicited public input on uses and exposure. EPA's documents and the public comments are in Docket EPA-HQ-OPPT-2019-0238. Additionally, information about the scope, problem formulation, and draft risk evaluation phases of the TSCA risk evaluation for this chemical is available at <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluation-14-dioxane>.

B. What is 1,4-dioxane?

1,4-dioxane is used primarily as a solvent in a variety of commercial and industrial applications like in the manufacture of other chemicals, as a processing aid, a laboratory chemical, and in adhesives and sealants. 2016 CDR data shows that there were two manufacturers producing or importing 1,059,980 pounds of 1,4-dioxane in the U.S. in 2015.

C. What input came from the public comment and peer review?

In response to the publication of the draft risk evaluation for 1,4-dioxane, published in September 2019, members of the SACC, as well as public commenters, highlighted potential omissions in the draft evaluation, specifically concerning 1,4-dioxane exposures when present as a by-product in consumer products and potential general population exposure from the ambient surface water pathway. In response, those conditions of use from the presence of 1,4-dioxane as a byproduct in consumer use and products are included in the scope of this supplemental analysis to the draft risk evaluation. Because the analytical approaches to assessing the unreasonable risk associated with these conditions of use mirror those used for the conditions of use evaluated in the September 2019 draft risk evaluation and there is not new or novel scientific information to consider, the Agency determined that additional peer review is not warranted. It is, however, appropriate to seek public comment for the supplemental analysis to the 1,4-dioxane draft risk evaluation that was not part of the original draft risk evaluation.

Additionally, in the September 2019 draft risk evaluation, an ambient water exposure pathway to general population exposure was excluded from the draft risk evaluation mistakenly on the premise that it was addressed by other EPA-administered authorities. In response to comments, EPA did evaluate hazards and exposures to the general population from ambient surface water for all the conditions of use in this supplemental analysis and the draft risk evaluation, and the unreasonable risk determinations for relevant conditions of use account for exposures to the general population via surface water. The exposures to general population via drinking water, ambient air and sediment pathways fall under the jurisdiction of other

environmental statutes administered by EPA, i.e., the Clean Air Act, 42 U.S.C. 7401 *et seq.*; the Safe Drinking Water Act, 42 U.S.C. 300f *et seq.*; the Comprehensive Environmental Response, Compensation, and Liability Act, 42 U.S.C. 9601 *et seq.*; and the Resource Conservation and Recovery Act, 42 U.S.C. 6901 *et seq.*

III. Request for Comment

The docket associated with this request contains the Supplemental Analysis to the Draft Risk Evaluation, the SACC Peer Review Report, and Supplemental Files to support the Revised Draft Risk Evaluation.

EPA is seeking public comment on, and information relevant to, the Supplemental Analysis to the Draft Risk Evaluation.

(Authority: 15 U.S.C. 2601 *et seq.*)

Andrew Wheeler,

Administrator.

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